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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/359,026 07/15/99 TOBIN

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EXAMINER

KRUSE, D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 09/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/359,026

Applicant(s)

TOBIN ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Claims 1, 2 and 4-9 in Paper No. 11 filed 2 November 2000 is acknowledged.
2. Claim 3 has been cancelled as requested in the Response filed 2 November 2000.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Drawings

4. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. The Draftsman has objected to the drawings as submitted, see the PTO 948 form attached.

Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825. Specifically, page 12 lines 14-17, page 19 lines 17-

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19, and page 20 lines 6, 7 and 27 of the Specification. Applicant must submit a CRF copy and paper copy of the Sequence Listing, a statement that the content of the paper and computer readable copies are the same and where applicable include no new matter as required by 37 C.F.R. § 1.821(e) or 1.821(f) or 1.821(g) or 1.825(d), as well as an amendment directing its entry into the specification.

Failure to comply with these requirements in response to this Office Action will result in ABANDONMENT of the application under 37 CFR § 1.821(g).

Claim Objections

6. Claims 5 and 7 are objected to because of the following informalities: At line 2 of Claim 5 and line 3 of Claim 7, the phrase "SEQ. I.D. 1" should be -- SEQ. I.D. No. 1 --. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1, 2 and 4 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The instant claims as presently worded read on a product of nature. Claim 1 should state -- An isolated nucleic acid --, Claim 2 should state -- An isolated host cell -- or -- A host cell transformed with --. Claim 4 reads on a product of nature.

9. Claim 5 is rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

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Specifically, a transgenic plant over expressing an antisense construct to SEQ. I.D. No. 1 that is not *Arabidopsis* would not have a specific and substantial asserted or well-established utility. It is unclear from the instant Specification that said antisense construct would have any effect on a transformed plant other than *Arabidopsis*.

Claim 5 is also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 7 and 8 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method comprising increasing the level of expression of protein kinase CK2, does not reasonably provide enablement for a method comprising transforming a plant with an antisense construct of SEQ. I.D. No. 1 or an antisense construct encoding SEQ. I.D. No. 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant claims methods of altering circadian rhythms and flowering in a plant comprising transforming said plant with a nucleic acid sequence comprising an antisense construct.

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Applicant teaches a method of altering the flowering time of *Arabidopsis thaliana* by over expressing a nucleic acid sequence encoding the *CKB3* gene isolated from *Arabidopsis* (page 19 second paragraph to page 24 first paragraph).

Applicant does not teach a method of altering circadian rhythms and flowering time of a plant by expressing an antisense construct of SEQ. I.D. 1 or of a nucleic acid that encodes SEQ. I.D. No. 2 or an amino acid sequence having at least 70% identity thereto, in a transformed plant.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has defined the gene product of *CKB3* as a Ser/Thr protein kinase, of which many are known in plants, said kinases are known to regulate protein activity and gene expression within plants by several mechanisms. At Claims 7 and 8, Applicant has not provided guidance for altering circadian rhythms and flowering time by expressing an antisense construct in a transformed plant. In addition, Applicant has provided no examples of expressing an antisense construct in a transformed plant. The art teaches that antisense RNA suppresses host RNAs in a sequence specific manner and that the manner in which an antisense RNA actually produces a desired effect is

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unclear (see Baulcombe 1996, Plant Molecular Biology 32:79-88, pages 81 and 82).

Therefore, without specific guidance, it is unclear if the claimed methods would operate in a transformed plant other than *Arabidopsis thaliana*, and would have required undue trial and error experimentation by one of skill in the art to transform a myriad of plant with the claimed antisense construct to determine in which plant the claimed method would alter circadian rhythms and flowering.

12. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 1, 2 and 4-9 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claim 1 the phrase "a coding sequence of SEQ. I.D. No. 1" is indefinite and does not state the metes and bounds of the claimed invention. The phrase should read -- the coding sequence --.

At Claim 2 lines 1 and 2, the term "heterologous" lacks a proper antecedent basis. Appropriate correction is required.

Claim 4 is indefinite for being depended on a cancelled claim. In addition, the term "heterologous at lines 1-3 lack a proper antecedent basis. At line 2 the phrase "of a heterologous polypeptide" appears to be in error and should read -- or a heterologous polypeptide --. Appropriate correction is required.

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At Claim 5 line 1, the phrase "a nucleic acid of SEQ. I.S. No. 1" is indefinite and does not state the metes and bounds of the claimed invention. The phrase -- the nucleic acid -- is suggested.

At Claim 6 line 2 and 3, the phrase "an amino acid" is indefinite and does not state the metes and bounds of the claimed invention. The phrase -- the amino acid -- is suggested.

At Claim 7 line 2, the phrase "a nucleic acid sequence of SEQ. I.D. No. 1" is indefinite and does not state the metes and bounds of the claimed invention. The phrase -- the nucleic acid -- is suggested.

At Claim 8 line 3, the phrase "an amino acid sequence of SEQ. I.D. No. 2" is indefinite and does not state the metes and bounds of the claimed invention. The phrase -- the amino acid sequence -- is suggested.

At Claim 9 line 2, the phrase "a level" is indefinite and does not state the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claim 4 is rejected under 35 U.S.C. § 102(b) as being anticipated by Collinge *et al* 1994 (Plant Molecular Biology 25:649-658).

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Collinge discloses a *Saccharomyces cerevisiae* host cell expressing a heterologous peptide, said peptide is a *Arabidopsis thaliana* casein kinase II β subunit which is 70% identical to Applicant's SEQ. I.D. No. 2. Hence, all of the claim limitations have been previously disclosed by Collinge.

16. Claim 9 is rejected under 35 U.S.C. § 102(b) as being anticipated by Carter *et al* 1991 (The EMBO Journal 10(8): 2063-2068).

Carter discloses a method of altering circadian rhythms in a plant comprising changing the level of activity of protein kinases, which would include CK2, within a plant by applying a protein synthesis inhibitor (see the Abstract on page 2063). In addition, Carter discloses the use of cycloheximide has been shown to affect protein synthesis and abolish circadian rhythms in plants (see page 2067, left column last paragraph). Because flowering in some plants is tightly controlled by circadian rhythms, Carter inherently discloses a method of altering flowering in a plant. Hence, all of the claim limitations have been previously disclosed by Carter.

Conclusion

17. No claims are allowed.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell can be reached at (703) 308-4310. The fax telephone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3482.

David H. Kruse, Ph.D.
21 September 2001


GARY BENZION
PRIMARY EXAMINER